K070644 1/2

510(k) SUMMARY

APR - 2 2007

Applicant:

W. L. Gore and Associates, Inc.
3250 W. Kiltie Lane
Flagstaff, AZ 86001

Contact:

Barbara L. Smith
Regulatory Affairs Associate

Date Prepared:

March 6, 2007

Proprietary Device Name:

GORE SEAMGUARD® Bioabsorbable Staple Line Reinforcement Material

Common Name: Staple Line Reinforcement Material

Classification: 21CFR 878.3300, FTL Class II

Device Predicate:

K053200 GORE SEAMGUARD® Bioabsorbable Staple Line Reinforcement Material for circular staplers

Device Description:

This 510(k) is being submitted for a minor modification to the product configuration made to the SEAMGUARD® Bioabsorbable Staple Line Reinforcement Material for use with circular staplers cleared under K053200. The proposed modification that is subject of this 510(k) submission is to include a polymer introducer sleeve as an accessory within the current packaging configuration for use as a tool to facilitate the delivery of the CBSG product through the abdominal wall to bariatric anastomotic sites during laparoscopic procedures. No other changes are being made to the SEAMGUARD device or its packaging as cleared under K053200.

Statement of Intended Use:

The GORE SEAMGUARD® Staple Line Reinforcement Material for circular staplers is indicated for use in surgical procedures in which a soft tissue anastomosis with staple line reinforcement is needed. GORE SEAMGUARD® Bioabsorbable Staple Line Reinforcement Material can be used for reinforcement of staple lines during bariatric, colon, colorectal, gastric, and small bowel procedures.

Note: The intended use of the modified device, as described in its labeling, has not changed as a result of the modification.

Technological Characteristics:

The sole difference between the predicate SEAMGUARD® device and the SEAMGUARD® device that is subject of this 510(k) submission is the optional introducer sleeve to be included with the SEAMGUARD® device.

Substantial Equivalence:

A variety of tests, assessments, and comparisons demonstrate that the SEAMGUARD® Staple Line Reinforcement Material with optional introducer sleeve for Circular Staplers is substantially equivalent to its predicate in terms of design, intended use, principle of operation, and performance attributes.

Differences between the predicate SEAMGUARD® device and the proposed SEAMGUARD® device with optional sleeve do not raise any significant issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

W.L. Gore & Associates, Inc.
% Ms. Barbara L. Smith
Regulatory Affairs Associate
301 Airport Road
P.O. Box 1408
Elkton, Maryland 21922-1408

APR - 2 2007

Re: K070644
Trade/Device Name: GORE SEAMGUARD® Staple Line Reinforcement Material for Circular Staplers
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: March 6, 2007
Received: March 8, 2007

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

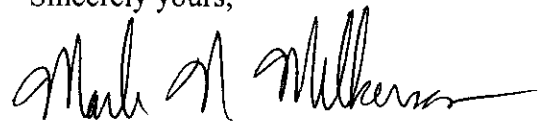
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K070644

Indications for Use

510(k) Number (if known): K070644

Device Name: GORE SEAMGUARD® Staple Line Reinforcement Material for Circular Staplers

Indications For Use:

The GORE SEAMGUARD® Staple Line Reinforcement Material for circular staplers is indicated for use in surgical procedures in which a soft tissue anastomosis with staple line reinforcement is needed. GORE SEAMGUARD® Bioabsorbable Staple Line Reinforcement Material can be used for reinforcement of staple lines during bariatric, colon, colorectal, gastric, and small bowel procedures.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070644